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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	00952-8033	8881
90628 7590 02/15/2012 Massachusetts General Hospital The General Hospital Corporation Perkins Cole LLP 700 13th Street, NW, Suite 600 Washington, DC 20005-3960				
EXAMINER BERMAN, SUSAN W				
ART UNIT 1765		PAPER NUMBER		
NOTIFICATION DATE 02/15/2012		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

09/764,445

Applicant(s)

MERRILL ET AL.

Examiner

/SUSAN W. BERMAN/

Art Unit

1765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-130 and 143-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-130, 143-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed 12-21-2011 have been fully considered but they are not persuasive with respect to the following issues.

The instantly claimed processes (claims 124, 125, 130,143 and 147) require (1) irradiating an UHMWPE fabricated article (2) heating the irradiated UHMWPE article to 150⁰C or above or above the melting point to crosslink the UHMWPE (3) cooling the crosslinked UHMWPE article and (4) forming an implant form the crosslinked UHMWPE a article. Sterilizing the implant is included in some claims. The instant product by process claims 126-127 rely upon the processes for patentability. Instant claims 128-129 rely upon the swell ratio and degree of oxidation properties for patentability of crosslinked UHMWPE and an implant comprising the crosslinked UHMWPE.

Shen et al (6,228,900, having an effective filing date of 07/09/1996) disclose the instantly claimed process steps and, thus, the products obtained by the process steps. **Hyon et al (6,168,626, having an effective filing date of 05/06/1996)** disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point and cooling, i.e., the steps set forth in instant process claim 147 and in instant claim 128 for obtaining the claimed product.

Applicant continues to argue that the instantly claimed process was disclosed by applicant in Application 08/600,744 to establish a prior filing date of 02-13-1996 for the instantly claimed process and products before the 07-09-1996 filing date of Shen et al

(6,228,900) and/or the 05-06-1996 filing date of Hyon et al (6,168,626). These arguments are unpersuasive for the following reasons.

Reduction to practice of the instantly claimed processes:

With respect to applicant's arguments regarding Example 6 is Application 08/600,744 to establish a prior filing date of 02-13-1996: What is disclosed in Example 6 in SN 08/600744, filed 02-13-1996, is that the UHMWPE sample was heated (melted) in a chamber and that an electron beam was irradiated into the chamber through the thin foil at top such that a maximum dose of 20 Mrad was received 5 mm below the surface of the polymer. Irradiation was done using a van de Graaff generator with electrons of energy 2.5 MeV and a dose rate of 1.67 Mrad/min. The heating was stopped and the sample allowed to cool to room temperature in the chamber after irradiation. Example 6 does not mention placing the chamber containing the sample on a conveyor belt or moving the chamber on a conveyor belt during irradiation or heating the irradiated UHMWPE sample to melt (150⁰C or above) after free radicals have been formed by irradiation and before cooling. Instead, Example 6 describes irradiation by a beam entering the chamber through the thin foil at the top of the chamber until maximum dose is reached. Example 6 further describes that the sample was removed from the chamber after the chamber and sample reached room temperature. **The method described in Example 6 does not suggest a process starting with irradiation to form free radicals and followed by heating to 150⁰C or above after irradiation to form crosslinks before cooling. Example 6 is an example of the disclosed process of melting UHMWPE and then irradiating the UHMWPE in the melt, followed by cooling. The instantly recited steps of irradiating an UHMWPE**

fabricated article followed by heating the irradiated article are not disclosed in Example 6 of 08/600,744.

With respect to Applicant's arguments and the Examiner's previous comments with respect to inherent functions and properties of a van der Graaff generator, these arguments and comments are not considered to be relevant to the instant claimed process or products. One reason is that the instantly claimed process does not require a conveyor belt or passing the sample through an electron beam to apply multiple doses or heating between doses. Applicant's arguments have been considered as an argument that the use of the van der Graaff generator in Example 6 discloses a process wherein the polyethylene is repeatedly heated and irradiated, thus providing evidence that the Example 6 process inherently requires irradiating followed by heating. This argument is not persuasive because applicant is relying upon a partial sequence that might be inherent to use of a van der Graaff generator for irradiation but ignores the disclosure that Example 6 is a process wherein the process required heating of the polyethylene sample followed by irradiation until the maximum dose was reached and then followed by cooling to room temperature. Therefore, applicant's argument that use of a van der Graaff generator in Example 6 inherently discloses the instantly recited process steps is not persuasive to establish an effective filing date of 02-13-1996 for the instant claims. The instantly claimed process steps are required to be in order of irradiating, then heating and then cooling while the process steps in disclosed in 08/600,744 Example 6 are required to be in the order heating, then irradiating and then cooling.

Rule 1.131 Declaration of Merrill et al filed 11-19-2009: Applicant's arguments that the evidence presented in the Rule 1.131 Declaration of Merrill et al filed 11-19-2009 shows

reduction to practice before January 20, 1995 is unpersuasive for reasons of record, Applicants point to sections 5 and 10 of the Declaration for evidence of conception and reduction to practice of the instantly recited method steps before January 20, 1995. Item b) of Exhibit 1 referred to in sections 5 and 10 of the Declaration discloses the concept of irradiation at room temperature to increase crosslinking in the amorphous zones and states that melting and recrystallizing will “probably again lead to the original crystal structure...and selective segregation of crosslinks into the amorphous regions”. However, this statement of basic motivation does not state subsequent melting was part of the process for crosslinking or provide evidence reduction to practice. Exhibit 3, Experiment 1, referred to in sections 12-14 of the Declaration discloses irradiation of solid UPE followed by DSC runs in set 2. The DSC thermal testing was carried out, according to Exhibit 3, Experiment 1, dated before 01-25-1995, to determine crystallinity levels of the irradiated UPE, not as a CIR-SM method to crosslink irradiated UHMWPE, as set forth in the instant claims and argued in the Declaration. The Examiner’s position, as previously stated, is that the DSC thermal analysis method for determining the melting and crystallization temperatures of irradiated UHMWPE by thermal analysis cannot be relied upon as evidence of reduction to practice of the process set forth in the instant claims. DSC thermal analysis is disclosed as a method of testing for melting and crystallization temperatures, not a method of treating irradiated UHMWPE to crosslink the irradiated UHMWPE. The instant claims recite irradiation to form free radicals followed by heating/melting to crosslink the UHMWPE, not melting and recrystallizing to determine melting and recrystallization temperatures. Thus, evidence of DSC thermal analysis is not considered evidence of reduction to practice of the instantly claimed process before January 20, 1995, as alleged by applicant. Section 10 is cited for

the statement that another “embodiment...to solve the wear problem” involved crosslinking polyethylene at room temperature by irradiation and subsequent melting, i.e., the “CIR-SM” process disclosed in Application 08/726,313, filed 10-02-1996. With respect to claims 128-129, the swell ratios reported in the Exhibit 6 are obtained by the method of melt-irradiation of UHMWPE.

Declaration of Orhun K. Muratoglu filed 11-19-2009: Applicant argues that Dr Muratoglu points to Exhibit 3, Experiment 2, in the Declaration of Merrill et al as evidence of reduction to practice of the instantly claimed process. Experiment 2 is said to provide evidence of a process requiring repeated steps of heating and irradiating consolidated polymer using a van der Graaff generator. This evidence is not persuasive for the following reasons. Experiment 2 discloses a process wherein UPE barstock is heated to 175°C, then irradiated to 1.0 Mrad followed by repeating the steps of heating and irradiating to a final step of irradiation to provide a total dose of 50 Mrad. The samples were evidently then analyzed using the DSC thermal testing. This experiment does not provide evidence of reduction to practice of the instantly claimed process, which requires irradiation of a fabricated article of UHMWPE to form free radicals, followed by heating the irradiated article in an oxygen-free atmosphere to a temperature of 150°C or greater to crosslink the irradiated UHMWPE, followed by cooling. Specifically, the instantly claimed process does not include heating to a temperature above 150°C before irradiation, multiple heating and irradiation steps and an irradiation step before the cooling step. The disclosure of heating after irradiation as part of a continuous process of heating and irradiating starting with heating and ending with irradiating is not considered to be a reduction to practice of the instantly claimed method.

Regarding inherency of process steps when using a van der Graaff generator presented to establish an effective filing date of 02-13-1996. The relevant passage in the MPEP with respect to inherent functions or properties in a disclosure is as follows: "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". In the instant case, the mere fact that the van de Graaff generator was used in Example 6 of 08/600,744 is not sufficient to establish that process steps in the order set forth in the instant claims were employed in Example 6.

MPEP §2163.07(a): the cited MPEP section states that an application may be amended to recite a function, theory or advantage of a device that inherently performs a function, operates according to a theory or has an advantage without introducing new matter. Thus applicant may amend the specification to include a known function of the van de Graaff generator. However, this section of the MPEP does not suggest amending the specification to introduce a method employing the known function that is materially different from the method that was originally disclosed.

Product claims 128-129: Applicant's argument that product claims 128-129 are supported by the disclosure of SN 08/600744 is unpersuasive. Example 4 discloses swell ratio for melt-irradiated UHMWPE (GUR 415), i.e. UHMWPE that was melted and then irradiated while molten (Example 2). Degree of oxidation at a given depth of crosslinked UHMWPE is not mentioned. Example 11, Tables 8 and 11 are not disclosed in 08/600744. The instant claims 128-

129 recite that the method is to irradiate UHMWPE, melt the irradiated UHMWPE and cool the UHMWPE, i.e. the claims do not recite irradiating UHMWPE in the melt, as disclosed in 08/600,744.

Claim Interpretation and Effective Filing Date

Claims 124-127, 130 and 143-149, recite a process wherein irradiation of UHMWPE to form free radicals is subsequently followed by heating or melting to crosslink the UHMWPE: a method (“IR-SM”) first disclosed in SN 08/726,313, filed 10-02-1996. Claims 124-127, 130 and 143-149, require that the irradiation step precede the heating or melting step, therefor, the effective filing date of the claims is 10/02/1996. The instant claims are considered to be fully supported by the disclosure of SN 08/726,313, but not by the disclosure of SN 08/600,744, filed 02-13-1996. In SN 08/600,744 a method of irradiating UHMWPE in the molten state is disclosed but a method of irradiation followed by heating/melting after irradiation of UHMWPE is not mentioned. Therefore, the earliest effective filing date of instant claims 124-127, 130 and 143-149 is considered to be the 10/02/1996 filing date of SN 08/726,313.

Claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN ‘744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN ‘744. SN ‘313 does disclose the swell ratio or degree of oxidation of the disclosed UHMWPE, therefor, the effective filing date for claims 128-129 is considered to be 10/02/1996.

The reasons why the statements and data in the Declarations of Merrill et al and Muratoglu, of record, do not establish reduction to practice of the processes and products as instantly claimed are discussed herein above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996).

Applicant's effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (effective filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129.

Claims 125-129 and 147 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and

127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reasons are that Hyon et al disclose the process steps set forth in claim 125 and the process steps in claim 124 except for sterilizing the implant and that the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps. With respect to claims 128-129, the process steps of irradiating, melting and cooling UHMWPE are taught by Hyon et al, therefor, the properties of the products would be expected to be within the instantly claimed ranges, in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the

invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 127 and 136 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims

of '362 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 125, 129, 130, 132-134, 136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /SUSAN W. BERMAN/ whose telephone number is (571)272-1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
2/6/2012

/SUSAN W BERMAN/
Primary Examiner, Art Unit 1765